

## Official Departmental Instructions

Effective screening, identification, and treatment of affected infants can best be accomplished through a team approach. Members of the “Newborn Screening Team” include:

- Parents
- Physician, Certified Nurse Midwife, Licensed Midwife, Physician Assistant or Nurse Practitioner
- Hospitals and Birthing Centers
- Department of Health and Environmental Control (DHEC)

These “team members” as well as their roles and responsibilities are described below.

### **Parents**

Parents are responsible for ensuring that their infant receives timely and appropriate primary and preventive health care. An important part of preventive health care for a newborn is the newborn screening test. Parents should be informed about the benefits of newborn screening and the process by which newborn screening is accomplished. This way they will know what to expect if their infant needs to have additional testing. In addition parents must be informed of the options that are available to them if they choose not to have their infant’s blood specimen stored and potentially used for confidential anonymous research. Parents are to receive the brochure *Newborn Screening For Your Baby’s Health* as the means to inform them of newborn screening and blood specimen storage options. This brochure may be ordered from the SC DHEC Material Library as noted on page 68. More information on this topic is included in the Hospitals and Birthing Centers section.

Newborn screening is mandated by law, and parents are held responsible to ensure that their infant is tested. Parents may only decline testing for religious reasons. A Parental Statement of Religious Objection (DHEC 1804) must be completed if parents refuse newborn screening. A copy of this three-part form is included on page 73. One copy should be maintained in the infant's medical record at the facility (hospital, physician's office or health department) where the screening was declined. The second copy is sent to DHEC’s Division of Women and Children's Services along with the mailing address of the parent. The third copy can be given to the parents. Upon receipt of the signed Parental Statement of Religious Objection, the Division of Women and Children's Services will send the parents a certified letter as a final attempt to offer newborn screening services.

### **Physician, Certified Midwife, Licensed Midwife, Physician Assistant or Nurse Practitioner**

The attending physician or certified midwife is responsible for the collection of the newborn screening specimen for all infants under his or her care in or outside of a hospital. Licensed midwives are likewise responsible for the collection of the specimen for infants under their care. Physician assistants and nurse practitioners may also be involved in the care of infants after birth. Collection of the specimen may be done under standing orders. Refusal of testing is discussed in the “Parents” section. It is very important that parents are informed of the newborn screening process and the results of the tests.

**As the newborn healthcare provider of record, the physician assumes responsibility for providing any necessary follow-up based upon the results of the newborn screening tests. This responsibility includes ensuring that any repeat specimen is collected as soon as possible**

**whether needed because the initial specimen was unacceptable or because the initial specimen showed an abnormality. Additionally, appropriate medical management and/or diagnostic testing must be done to avoid potential morbidity in those infants with abnormal newborn metabolic screening.**

If the physician of record will not be providing follow-up care for an infant, he or she **must** notify the Division of Women and Children's Services and provide the name of the physician who will be providing follow-up care. If the physician of record does not know the name of the physician who will be providing follow-up care, DHEC staff will make every reasonable effort to locate the infant and obtain a repeat specimen. **It is vital that notifications regarding change in physician are made in a timely manner to ensure that no affected infants are missed.**

Additionally, every office providing health care to infants should have procedures in place to ensure that newborns presenting for an initial visit, whether for routine preventive care or related to an illness, have the office records checked for the newborn screening results. If these results are not found in the record, the office should call Women and Children's Services to ascertain the screening status of the infant.

The physician is responsible for initiating appropriate medical follow-up and diagnosis of infants with abnormal test results. This may include referral to medical specialists. The physician should also refer parents for genetic counseling when appropriate. If prompt treatment or referral is not possible, the physician shall notify Women and Children's Services. **In addition, it is the responsibility of the physician to notify DHEC of the final diagnosis of the infant and the date treatment was initiated. This includes notification if the initial screening test was determined to be a false positive result based upon further diagnostic work up.** To assist in this process, a letter requesting this information is sent from Women and Children's Services to the physician approximately 3 months after the initial screening test result is known.

### **Hospitals and Birthing Centers**

Designated hospital personnel are responsible for collection of blood spot specimens for all infants delivered in the hospital. The hospital shall send the specimens to the DHEC Bureau of Laboratories, Newborn Screening Laboratory.

Hospital personnel shall use the blood collection procedures established by the Clinical and Laboratory Standards Institute. This procedure, Blood Collection on Filter Paper for Newborn Screening Programs: Approved Standard—Fifth Edition, LA4-A5, is described on pages 10-11. Designated hospital personnel shall complete the demographic information on the laboratory test slips as accurately and completely as possible. **It is very important that the infant's name appear on the newborn screening collection form exactly as it is to be recorded on the birth certificate. Discrepancies between the name recorded on the newborn screening collection form and the legal name of the infant can cause delays in locating an infant who needs a repeat test. Hospital staff shall confirm the legal name of the infant with the mother before recording it on the newborn screening collection form.**

**The newborn screening collection form is a legal record. The submitter is legally responsible for the accuracy and completeness of the information it contains.**

**Hospital staff shall inform the parent or legal guardian about the state law mandating the screening and about the newborn screening process. Blood specimens are required by law to be**

**stored a minimum of two years and potentially used for confidential anonymous research UNLESS the parent or legal guardian objects. Information about blood specimen storage and use options is required to be given to a parent or legal guardian. The process outlined below should be followed.**

1. There are three DHEC forms or brochures that are used in the newborn screening collection and parent information processes. These include:
  - a. *Newborn Screening for Your Baby's Health*, a brochure that explains the newborn screening process and the blood specimen storage and use options. Ordering information is found on page 68. This brochure shall be given to the parent or legal guardian.
  - b. Blood Sample Storage Options Form, DHEC 1812. A copy of this form and its instructions is found on page 75. Ordering information is found on page 67.
  - c. Newborn Screening Collection Form, DHEC 1327. A copy of this form and its instructions is found on page 70. Ordering information is found on page 67.
2. Staff should inform the parent or legal guardian that a blood specimen for the purposes of newborn screening has been or will be collected. Staff shall give the parent or legal guardian the brochure *Newborn Screening for Your Baby's Health* as the means of providing information on the newborn screening process and the blood specimen storage and use options.

Parent or legal guardian does not object to blood specimen storage and use.

- a. Staff shall sign and date the Blood Sample Storage Options Form, DHEC 1812 in the appropriate space to document that the required information was given to the parent or legal guardian. (In most instances this form will be found and completed on the back of the Newborn Screening Collection Form, DHEC 1327.)
- b. If the parent or legal guardian does not object to storage and use of the infant's blood specimen, no other signature needs to be documented on the Blood Sample Storage Options Form.
- c. If the Blood Sample Storage Options Form is not found on the back of the collection form, staff will attach the Blood Sample Storage Options Form to the back of the Newborn Screening Collection Form using the adhesive strip located at the top of the Blood Sample Storage Options Form.
- d. All forms, including the Blood Sample Storage Options Form and the Newborn Screening Collection Form, are to be mailed to the DHEC Newborn Screening Laboratory. See pages 9-14 for more information on collecting and handling blood specimens.

Parent or legal guardian objects to blood specimen storage and use.

- a. Staff shall sign and date the Blood Sample Storage Options Form, DHEC 1812 in the appropriate space to document that the required information was given to the parent or legal guardian. (In most instances this form will be found and completed on the back of the Newborn Screening Collection Form, DHEC 1327.) Hospital staff may opt to use the full sized version of the Blood Sample Storage Options Form to avoid having the parent handle the blood collection form.

b. If the parent or legal guardian does not want the infant's blood specimen stored and potentially used for confidential anonymous research, the parent or legal guardian must complete the appropriate sections of the Blood Sample Storage Options Form.

c. If the Blood Sample Storage Options Form found on the back of the collection form is not used, staff will attach the full sized version of the Blood Sample Storage Options Form to the back of the Newborn Screening Collection Form using the adhesive strip located at the top of the full sized version of the Blood Sample Storage Options Form.

d. All forms, including the Blood Sample Storage Options Form and the Newborn Screening Collection Form, are to be mailed to the DHEC Newborn Screening Laboratory. See page 9-14 for more information on collecting and handling blood specimens.

Parent or legal guardian is not available to receive the required information before the blood specimen needs to be mailed to the DHEC Newborn Screening Laboratory.

a. In some instances, the blood specimen will need to be collected and mailed before the parent or legal guardian is available to receive the information about blood specimen storage and use. This will most often occur when an infant is transferred from the hospital of birth to another hospital because of prematurity or illness.

b. The blood specimen should be collected and mailed to the DHEC Newborn Screening Laboratory, but staff should not sign the Blood Sample Storage Options Form because the information has not been given to the parent or legal guardian.

c. When the parent or legal guardian is available, staff shall give the brochure *Newborn Screening for Your Baby's Health* as the means of providing information on the newborn screening process and the blood specimen storage and use options.

d. Staff shall then sign and date the Blood Sample Storage Options Form, DHEC 1812 in the appropriate space to document that the required information was given to the parent or legal guardian. Staff should use the version of the form that is not attached to the collection form. Care must be taken to ensure that the demographic information on the Blood Sample Storage Options Form matches that documented on the collection form that had previously been mailed to the DHEC Newborn Screening Laboratory.

e. If the parent or legal guardian does not object to storage and use of the infant's blood specimen, no other signature needs to be documented on the Blood Sample Storage Options Form.

f. If the parent or legal guardian does not want the infant's blood specimen stored and potentially used for confidential anonymous research, the parent or legal guardian must complete the appropriate sections of the Blood Sample Storage Options Form.

g. The completed form can be mailed in the same envelope as the other newborn screening forms.

**The provision of the screening test is covered under the general informed consent or authorization signed by the parents at the hospital. No specific consent or authorization needs to be obtained prior to collecting a specimen for newborn screening. Refusal of testing is discussed in the "Parents" section.**

The hospital shall screen all infants regardless of their length of stay. If for some reason the infant was not screened, the hospital staff shall complete the newborn screening collection form demographic information and write at the top "Specimen Not Collected." This form shall be sent to Women and Children's Services or to the Bureau of Laboratories. If the infant is to be discharged before 24 hours of age, a specimen shall be collected as close to discharge as possible. The parents shall be informed that retesting is necessary within one week of age. The initial test, regardless of its validity, is the only mechanism available to assure that the infant can be identified for future follow-up if necessary.

If the infant is to receive a transfusion, a specimen should be collected before transfusion when possible, even if it means that the specimen is collected before 24 hours of age. This will allow for more accurate screening for hemoglobinopathies and galactosemia. The test results shall be recorded in the infant's record. The hospital administrator, or his designee, shall review each infant's record no later than 10 days after delivery to assure that a specimen was submitted and that a report was received.

### **DHEC**

Within the agency, there are three units that contribute to the operation of newborn screening services: the Bureau of Laboratories, Women and Children's Services and the region/county health departments.

The Bureau of Laboratories, Division of Chemistry, Newborn Screening Laboratory is responsible for analysis of blood specimens for newborn screening for all infants born in South Carolina. When abnormal test results are found, the Laboratory notifies Women and Children's Services so that further testing and/or other diagnostic procedures can be arranged with the appropriate health care provider. Test results are sent to the hospital/other submitter and the physician indicated on the collection form. The names of infants with test results indicative of hemoglobinopathy traits are also sent to the designated regional sickle cell community based organization.

Women and Children's Services is responsible for providing follow-up recommendations to physicians, maintaining follow-up tracking systems, monitoring screening processes, and establishing follow-up protocols. Depending upon the severity of the abnormal screening result, the attending physician will receive either phone notification or mail notification from Women and Children's Services regarding an infant with an abnormal test result.

Each health region has a newborn screening coordinator and a nutritionist designated to provide necessary follow-up services. When a physician is unable to locate an infant who needs further testing or treatment, the physician shall notify Women and Children's Services. Women and Children's Services will then contact the appropriate newborn screening coordinator. The coordinator is responsible for making reasonable efforts to locate the infant for further services. These services may include specimen collection, parent education, and specialty care referrals. The nutritionist may assist in the management of persons with metabolic disorders.